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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,114	06/16/2005	David Frederick Horrobin	P70482US0	8859

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EXAMINER	
SIMMONS, CHRIS E	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,114	HORROBIN ET AL.	
	Examiner	Art Unit	
	Chris E. Simmons	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/27/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In this case, it is unclear whether eicosapentaenoic acid (EPA) is in a composition along with other components or whether EPA is the only component being administered. Using "comprising" or "containing" to properly define the composition would overcome this particular issue of indefiniteness in claim 1.

For examination, it will be interpreted that claim 1 reads on a composition comprising EPA.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 provides for the use of EPA, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether

the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 6 recites the broad recitation "in which the EPA is more than 70%", and the claim also recites "preferably more than 90%" and then recites "very preferably more than 95%" which is the narrower statement of the range/limitation.

In the present instance, claim 10 recites the broad recitation "given at a dose between 50mg and 20g/day", and the claim also recites "preferably between 100mg and 5g/day" and further recites "very preferably between 300mg and 3g/day" which is the narrower statement of the range/limitation.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In this case, claim 1 recites the limitation "treating anorexia nervosa, bulimia and related clinical syndromes". It is unclear whether the Applicant's intent is to treat anorexia and bulimia in the same patient or if anorexia alone can be treated in one patient and bulimia alone can be treated in a another patient. By reciting "and" to connect the different diseases and clinical syndromes, it appears as EPA can be given to treat anorexia, bulimia and the clinical

syndromes related to bulimia in the same patient at the same time. Are the "related clinical diseases" related only to bulimia or does Applicant intend to treat the related clinical syndromes of anorexia as well? It may be more clear if claim 1 is rewritten to read: "A method of treating anorexia nervosa and related clinical syndromes or bulimia and related syndromes by administering a composition comprising eicosapentaenoic acid in any appropriate form which can be assimilated by the body".

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In this case, the recitation of the phrase "and related clinical syndromes" is indefinite. It is unclear exactly what syndromes Applicant considers to be "related" to bulimia and anorexia.

Claim 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6-12 recite the limitation "or use" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In this case, the recitation of "the EPA contains less than 10% in aggregate and less than 3% individually of docosahexaenoic acid and linoleic acid" in claim 7 is indefinite because EPA is a compound and cannot contain any other compound.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any

inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 USC 103(a) as being unpatentable over **WO/2000/044361** ('361) in view of **Jatoi et al**. ("Jatoi", "*Current management of cancer-associated anorexia and weight loss*"; Oncology (Williston Park). 2001 Apr;15(4):497-502, 508; discussion 508-10.) in further view of **Casper, RC** ("Casper", "*Depression and Eating Disorders.*"; Depress Anxiety; 1998; 8 Suppl. 1:96-104.).

Determination of the scope and content of the prior art (MPEP 2141.01)

'361 teaches a pharmaceutical preparation comprising EPA in an appropriately assimilable form where of all the fatty acids present in the preparation at least 90%, and preferably at least 95%, is in the form of EPA and where less than 5%, and preferably less than 3% is in the form of DHA or any other fatty acid which may compete with EPA (page 3, lines 4-16) is provided for the treatment of a psychiatric or central nervous disorder. The preparation may be administered with conventional drugs to treat psychiatric or central nervous disorders to improve their efficacy or reduce their side effects (abstract; instant claims 1-3 and 6-8). The psychiatric disorder or nervous system disorder may be

depression or anxiety (claims 8-9 and 23-24) and EPA may be in the form of ethyl EPA (claim 4; instant claims 4 and 5). '361 also teaches that EPA is preferably the ethyl derivative (claims 4; instant claims 4-5 and 9) and may be given at dosage of 1g/day (page 13, lines 16-20) or when supplied alone, the useful daily dose of EPA may be in the range of 0.05 g to 50 g/day, preferably 0.1 g to 10 g/day and very preferably 0.5 g to 5 g/day. (page 37, lines 7-9; instant claim 10) . The composition may be administered orally via delivery systems known to those skilled in the art; it may also be administered intravenously, intramuscularly, and by other parenteral routes (page 25, line 22 to page, line 6; instant claims 11 and 12).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

'361 does not expressly disclose treating anorexia nervosa and bulimia.

Finding of prima facie obviousness

Jatoi teaches in the abstract that EPA intervention has promise to replenish lean tissue in patients suffering from anorexia or weight loss.

Casper teaches in the abstract the prominence of depressive symptoms and depressive disorders in eating disorders such as anorexia and bulimia.

At the time, it would have been obvious to one of ordinary skill in the art to use the composition as claimed to treat anorexia, bulimia or related clinical syndromes.

Rational and Motivation (MPEP 2142-2143)

The motivation would have been to make a composition with high amounts of EPA to treat those suffering from increased weight loss who are

reluctant to orally ingest. The patient is much more likely to comply with the lower volumes required with the highly purified compound (see '361, page 12 line 18-20). Also the purer the preparation of EPA the more likely is it to occupy the relevant active binding sites, and the more likely is it to be able to have desirable biological effects.

The claims would have been obvious because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-12 are rejected under 35 USC 103(a) as being unpatentable over **WO/2000/044361** ('361) in view of US 2002/0099020 ('020).

Determination of the scope and content of the prior art (MPEP 2141.01)

'361 teaches a pharmaceutical preparation comprising EPA in an appropriately assimilable form where of all the fatty acids present in the preparation at least 90%, and preferably at least 95%, is in the form of EPA and where less than 5%, and preferably less than 3% is in the form of DHA or any other fatty acid which may compete with EPA (page 3, lines 4-16) is provided for the treatment of a psychiatric or central nervous disorder. The preparation may be administered with conventional drugs to treat psychiatric or central nervous disorders to improve their efficacy or reduce their side effects (abstract; instant claims 1-3 and 6-8). The psychiatric disorder or nervous system disorder may be depression or anxiety (claims 8-9 and 23-24) and EPA may be in the form of ethyl EPA (claim 4; instant claims 4 and 5). '361 also teaches that EPA is preferably the ethyl derivative (claims 4; instant claims 4-5 and 9) and may be given at dosage of 1g/day (page 13, lines 16-20) or when supplied alone, the useful daily dose of EPA may be in the range of 0.05 g to 50 g/day, preferably 0.1 g to 10 g/day and very preferably 0.5 g to 5 g/day. (page 37, lines 7-9; instant claim 10) . The composition may be administered orally via delivery systems known to those skilled in the art; it may also be administered intravenously, intramuscularly, and by other parenteral routes (page 25, line 22 to page, line 6; instant claims 11 and 12).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

'361 does not expressly disclose treating anorexia nervosa and bulimia.

Finding of prima facie obviousness

'020 discloses a method of treating cachexia and/or anorexia using a composition comprising EPA (claims 1 and 6-8).

At the time of the invention it would have been obvious to a person of ordinary skill in the art to use the composition as claimed to treat anorexia bulimia or related clinical syndromes.

Rational and Motivation (MPEP 2142-2143)

The motivation would have been to make a composition with high amounts of EPA to treat those suffering from increased weight loss who are reluctant to orally ingest. The patient is much more likely to comply with the lower volumes required with the highly purified compound (see '361, page 12 line 18-20). Also the purer the preparation of EPA the more likely is it to occupy the relevant active binding sites, and the more likely is it to be able to have desirable biological effects.

Therefore it would have been obvious to combine the cited references to obtain the claimed invention as specified in the claims.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore,

the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Pertinent art not relied upon for current office action:

- Barber et al., "The effect of an oral nutritional supplement enriched with fish oil on weight-loss in patients with pancreatic cancer", British Journal of Cancer (1999): 81(1), 80-86.
- Eduardo Bruera, "ABC of palliative care: Anorexia, cachexia, and nutrition"; BMJ 1997 (8 November);315:1219-1222

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571) 272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chris Simmons
Patent Examiner
AU 1614

August 27, 2007

9/2/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

/CS/